

Remarks

Claims 15, 17, 18, 20, 21 and 33-38 were pending in the subject application. By this amendment, claim 15 has been amended and claims 17 and 33 have been cancelled. Support for the amendments can be found throughout the application and claims as originally filed. No new matter has been added by these amendments. Accordingly, claims 15, 18, 20, 21, and 34-38 are currently before the Examiner for consideration. Favorable consideration is respectfully requested.

The amendments presented herein have been made to lend greater clarity to the claimed subject matter and to expedite prosecution of the subject application to completion. These amendments should not be construed as an indication of the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 15, 17, 19, 21 and 33-38 have been rejected under 35 U.S.C. §112, first paragraph. The applicants respectfully traverse this ground for rejection to the extent that it might be applied to the claims as amended herein. The skilled artisan having the benefit of the applicants' disclosure, could readily, and without undue experimentation practice the full scope of the invention as now claimed.

It is important to bear in mind that for an invention to be enabled under the first paragraph of §112, the specification need only teach a person of ordinary skill in the art "how to make" and "how to use" the invention.

The Office Action states that the specification does not provide enablement for the use of all antibiotics in the claimed method. Without necessarily agreeing with the analysis as set forth in the Office Action, in order to expedite prosecution and to lend greater clarity to the claimed subject matter, the claims have been amended herein to recite the use of specific antibiotics.

It should be noted that the requirement for some experimentation and/or screening does not necessarily make a claim non-enabled. "Enablement is not precluded by the necessity for some experimentation such as routine screening. . . . A considerable amount of experimentation is permissible, if it is merely routine . . ." (emphasis added). *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988).

The applicants appreciate the Examiner's indication that the specification enables the use of "fluoroquinolones such as moxifloxacin, tetracyclines such as mezlocillin, and imipenem." Please note that claim 15 has been amended herein to recite the use of beta-lactams (of which mezlocillin is an example), carbapenem (of which imipenem is an example), and fluoroquinolones. The skilled artisan could readily, and without undue experimentation, use these antibiotics in the claimed method.

Therefore, the applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

Claim 33 has been rejected under 35 U.S.C. §112, first paragraph. Claim 33 has been cancelled herein, thereby rendering moot this ground for rejection.

Claims 15, 17, 18, 20, 21 and 32-38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over P. Langhorne *et al.* (Age and Ageing 2002) in view of Fong (*The Journal of Infectious Diseases*, 2000, Vol. 181, Suppl. 3, pp. S514-S518). The applicants respectfully traverse this ground for rejection because the cited references, taken either alone or in combination, do not disclose or suggest the use of an anti-infective agent to reduce lethality and morbidity from pneumonia, urinary tract infection, and/or sepsis, in patients who have just had a stroke.

The method of the present invention involves the administration of an anti-infective therapy to a patient shortly after (within 72 hours) that patient has suffered an acute stroke. The therapy is applied soon after the occurrence of the stroke and is applied, contrary to the teachings of prior art, even in the absence of an established infection. Surprisingly and advantageously the method of the subject invention reduces lethality and morbidity from pneumonia, urinary tract infection, and/or sepsis, in stroke patients.

The Langhorne *et al.* (2000) reference summarizes clinical studies published between 1985 and 2000 from 11 stroke units. With respect to acute units, some units had excluded subgroups of patients (see page 366, right column, "exclusion criteria"). Furthermore, from a review of the "acute assessment" protocol (see page 367, right column), there is no indication that the patients recently had a stroke (which is an essential feature of the invention as claimed by the current applicants).

Upon a close look at Table 4 on page 369 and the “early management” paragraph on page 368, it can be seen that an antibiotic is administered in the event of a “suspected” infection. The Office Action states that “[i]n regard to claims 34 and 38, the disclosure of suspected infection is interpreted to read on no clinical signs of infection or occurrence of bacterial infection.” The applicants respectfully submit that this interpretation cannot be correct. Certainly, an infection would not be “suspected” unless there were clinical symptoms (as is required by claim 34). Nor would an infection be “suspected” if there was, in fact, no infection at all (as is required by claim 38).

What is being described by Langhorne *et al.* is the situation where there are clinical symptoms (e.g. fever) but, perhaps, confirmatory assays have not yet been completed (thus the infection is “suspected” but not confirmed). This is very different from what is claimed in claim 34 (no symptoms) and 38 (no infection).

The Langhorne *et al.* reference provides no indication that antibiotics are, or should be, administered, as a matter of course, immediately following a stroke, and even in the complete absence of any indication that an infection is present. That is the crux of the current invention.

The Fong (2000) reference discloses the association between Chlamydia infection and complications of (amongst others) stroke (abstract). The publication pertains almost entirely to chronic bacterial infections that are the cause of the stroke (e.g. through atherosclerosis) (see page S514, left column, line 8). Thus, the infection is already present at the time of the acute stroke. This is completely different from the present invention.

The Fong reference pertains to the use of moxifloxacin for the prevention of atherosclerotic lesions of the aorta following an infection (see page S516, left column, first full paragraph). The teachings of Fong may be relevant for efforts to develop treatments against atherosclerosis for patients suffering from chronic bacterial infections but they are not relevant to patients who have just suffered a stroke. Specifically, Fong does not disclose or suggest a method of treatment following an acute stroke in a patient not having a pre-existing chronic infection.

It is well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant’s invention does not make the modification or application obvious unless “there was an apparent reason to combine the known

elements in the fashion claimed” by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_\_ (2007). In this case, the applicants respectfully submit that there is no reason to modify the cited references to arrive at the current invention and, thus, there is no *prima facie* case of obviousness.

Since Fong does not make reference to stroke except as indicated above, a person of skill in the art would have had no reason to link the teachings of Fong with a method for anti-infective therapy after acute stroke. Also, unlike the teachings of Fong, the present invention is not related to chronic infections that are present before a stroke occurs. Accordingly, there would be no reason to combine the teachings of Fong with those of Langhorne *et al.* and, even if the combination were made, it would not lead to the current invention.

As amended herein, the applicants’ claims are drawn to the use of specific antibiotics administered during a narrow window of time to treat very specific conditions. The cited references, either taken alone or in combination, do not disclose or suggest the claimed method of treating stroke wherein lethality and morbidity from pneumonia, urinary tract infection, and/or sepsis, are reduced by administering specific antibiotics shortly after a stroke occurs.

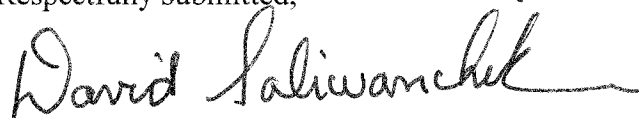
Therefore, the applicants respectfully request reconsideration and withdrawal of the obviousness rejection under 35 U.S.C. §103 based on P. Langhorne *et al.* and Fong.

In view of the foregoing remarks and amendments to the claims, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

A handwritten signature in black ink, reading "David Saliwanchik". The signature is fluid and cursive, with a long horizontal stroke at the end.

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